UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,483	08/02/2001	Steven Finkbeiner	UCAL161DIV	7273

7590 05/20/2003

Bret E. Field
Bozicevic, Field and Francis LLP
Suite 200
200 Middlefield Road
Menlo Park, CA 94025

EXAMINER	
WINKLER, ULRIKE	
ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,483	FINKBEINER, STEVEN	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-24* is/are pending in the application.

4a) Of the above claim(s) *14-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that groups I-III all require the use of an antibody; therefore, it would not be serious burden for the examiner to search all groups together. This is not found persuasive because the claims are directed to methods, which require the examination of the specific sequential method steps set out in the claims.

The requirement is still deemed proper and is therefore made FINAL.

Specification

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 6, is attached to the instant Office Action.

Claim Objections

Claim 10 is objected to because of the following informalities: The claim is dependent on a canceled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 10, it is not clear from the claimed preamble or the specification what is intended by "a target". The specification suggests that the target of huntingtin protein a cellular protein. The claim construction, however, indicate that the target is an antibody. Clarification of what is intended by "target" is required.

In Claim 10 it is not clear what is intended with "a first compound that is said protein or binding fragment or mimetic thereof". From the claim is construction it appears that "a first compound that is said protein or binding fragment or mimetic thereof" is the polyglutamine expansion comprising protein. However, the specification does not provide any binding fragments or mimetic of the polyglutamine expansion comprising protein. Clarification of what is intended by "a first compound" is required.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The preamble of the claim is directed identify compounds capable of modulating the interaction between mutant huntingtin protein and its (cellular) targets. Yet the method steps outlined in the claim will only measure the interaction between mutant huntingtin protein and an antibody, antibodies are not the normal cellular target of the huntingtin protein.

To comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must enable one skilled in the art to make and use the claimed invention without undue experimentation. The claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims. Such an analysis does not need to specifically enumerate (points 1-8) but only needs to have a select few of the factors present discussed in a rejection.

The specification shows (pages 17-18) monoclonal antibodies developed according to the protocol set out in Example I and designated 1F11E5, 4H7H7, 3A2D3, 4F1B5, 3C4A6, 3B5H10.

These monoclonals were all compared to the 1C2 antibody by western blot. The amount of the 1C2 antibody necessary to generate a comparable western blot signal was always greater than the amount of 1F11E5, 4H7H7, 3A2D3, 4F1B5, 3C4A6 and 3B5H10 antibodies needed. The results indicate that the antibodies are specific for mutant huntingtin over wild-type huntingtin, even when they are in their native conformations.

Claim meets the utility requirement of 35 U.S.C. § 101. Only one specific, substantial, and credible utility is required to support the requirements of 35 U.S.C. § 101. In the instant cased the presence of an antibody recognizing a polyglutamine expansion is useful in diagnostic methods relating to Huntington's disease.

While the claimed antibody meets the utility requirement of 35 U.S.C. § 101 the claimed invention does not comply with the "how to use" prong of 35 U.S.C. § 112, first paragraph. The specification does not teach a method of screening agents that will interfere with the interaction of mutant huntingtin protein with the normal cellular target of the huntingtin protein. The method steps merely indicate that the agent may interfere with the antibody binding to the polyglutamine expansion protein, yet the methods cannot distinguish whether the agent bind to the antibody or the polyglutamine containing protein.

The prior art teaches that the mAB 1C2 specifically recognizes polyglutamine expansions in soluble huntingtin. However, the antibody does not recognize insoluble high molecular weight polyglutamine expansions. Indicating that 1C2 recognizes an elongated polyglutamine tract but not when in an a fibrillar conformation (see Heiser et al. IDS Paper No. 6, page 6740). The reference teaches a screening assay that interferes with the self aggregation of huntingtin which is thought to be the cause of the neurodegenerative disease. The reference indicates that

1C2 (monoclonal) antibody, HD1 (polyclonal) antibody as well as Congo Red are able to prevent the huntingtin protein from aggregating (see Heiser et al. IDS Paper No. 6, page 6741). There is no correlation in the prior art or the instant specification which would indicate that a compound that interferes with the antibody binding to the polyglutamine expansion of huntingtin would interfere with the binding of the polyglutamine expansion protein to the normal cellular target. A compound that interferes with the antibody binding to the polyglutamine expansion protein can act on the antibody alone or it can bind to the polyglutamine expansion protein, only those that bind to the polyglutamine expansion protein may effect the binding of the protein to the cellular target. However, the instantly claimed method cannot determine to which protein the agents binds, therefore, the claimed method cannot determine if the agent is capable of modulating the interaction between the polyglutamine expansion protein and the cellular target.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER

7/29/03